

Application No. 10/802,906
Amendment dated August 7, 2006
Reply to Office Action of March 20, 2006

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REMARKS

Applicant amended the title and claim 7 to further define Applicant's claimed invention.

In the Office Action, the Examiner rejected claims 7-41 under the judicially created doctrine of obviousness-type double patenting over:

claims 1-221 of U.S. Patent No. 6,592,586;
claims 1-20 of U.S. Patent No. 6,926,718;
claims 1-39 of U.S. Patent No. 6,936,050;
claims 1-39 of U.S. Patent No. 6,936,051;
claims 1-220 of U.S. Patent No. 6,527,776;
claims 1-124 of U.S. Patent No. 6,454,771;
claims 1-117 of U.S. Patent No. 6,398,783;
claims 1-25 of U.S. Patent No. 6,139,550; and
claims 1-173 of U.S. Patent No. 6,193,721.

The Examiner provisionally rejected claims 7-41 under the judicially created doctrine of obviousness-type double patenting over:

claims 1-20 of co-pending Application No. 11/110,161;
claims 31-44, 174, 175, and 232-245 of co-pending Application No. 10/160,059;
claims 1, 3-8, 11-18, 20-24, 26-60, 65-81, 199-215, 217-237, 242-252, 254-256, and 261-363 of co-pending Application No. 10/160,247; and
claims 1-8, 11-75, 183-188, 190-193 195-197, 201-241, and 244-277 of co-pending Application No. 10/160,407.

Applicant is submitting concurrently with this reply a Terminal Disclaimer disclaiming the term of any patent granted on the present application that would extend beyond the term of U.S. Patent No. 6,139,550, thereby rendering the Examiner's rejection in view of the '550 patent moot. Applicant respectfully traverses the Examiner's rejections as to the remaining patents and applications listed above (the "listed patents and applications") for at least the reasons set forth below.

Application No. 10/802,906
Amendment dated August 7, 2006
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I. The claims of the present application and the claims of the listed patents and applications are directed to inventions in different fields of surgery.

Independent claim 7, as now amended, recites "an orthopedic implant for engaging at least one bone of the human body outside of the human spine." All the independent claims from the remaining listed patents and applications, with the exception of the independent claims of U.S. Patent No. 6,527,776, are directed to inventions for application in the "anterior human cervical spine." The distinctness of the claims of the '776 patent are discussed below. Applicant submits that the field of spinal surgery and other fields of skeletal surgery outside of the spine are distinct and non-analogous. Accordingly, Applicant submits that the claims of the present application would not have been obvious in view of the claims of the listed patents and applications.

II. The claims of the present application are mutually exclusive relative to those of the listed patents and applications.

Independent claim 7 of the present application recites "a substantial portion of said bone-contacting surface being one of flat and convex along the length of said body." According to the MPEP, "[t]he general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first." (MPEP § 806.04(f) "Claims Restricted to Species, by Mutually Exclusive Characteristics" (August 2001)). The bone-contacting surface being one of flat and convex as recited in claim 7 of the present application is a feature that is exclusive to areas outside of the anterior cervical spine due to the concave curvature of the anterior cervical spine. All the independent claims from the remaining listed patents and applications, with the exception of the independent claims of the '776 patent, are directed to inventions for application in the "anterior human cervical spine." The distinctness of the claims of the '776 patent are discussed below. Accordingly, Applicant submits that the claims of the present application and those of the listed patents and applications are directed to

Application No. 10/802,906
Amendment dated August 7, 2006
Reply to Office Action of March 20, 2006

inventions having mutually exclusive characteristics and are therefore patentably distinct.

III. The claims of the present application are not "generic" to the claims of the listed patents and applications.

The Examiner contends that "the inventions of the patents are in effect a 'species' of the 'generic' invention of claims 7-41 in the application." (Office Action, page 3, paragraph 1). As set forth above, independent claim 7 is directed to "an orthopedic implant for engaging at least one bone of the human body outside of the human spine." All the independent claims from the remaining listed patents and applications, with the exception of the independent claims of the '776 patent, are directed to inventions for application in the "anterior human cervical spine." The distinctness of the claims of the '776 patent are discussed below. Applicant submits that the claims of the present application are not "generic" to the claims of the listed patents and applications, and therefore are not "anticipated" by the "species" of the listed patents and applications.

IV. The claims of the '776 patent and U.S. Patent No. 6,592,586 are patentably distinct from the subject matter of the present application.

The claims of the present application are drawn to an implant including a locking element for locking at least two bone screws. The claims of the '776 patent are directed to a locking element adapted to retain at least two bone screws. The claims of the '586 patent are directed to an anterior cervical plate system including a plate and a plurality of locking elements that are each adapted to lock to the plate only one bone screw. The '776 and '586 patents are divisionals of U.S. Patent No. 6,193,721. During prosecution of the '721 patent, the Office mailed a Restriction Requirement restricting the claims. A copy of the Restriction Requirement is attached hereto as **Exhibit A**. The Restriction Requirement designated at least the following subject matter as patentably distinct: (1) a plate system including a plate with a locking element adapted to lock at least two bone screws (species (a)); (2) a locking element (Group VI); and (3) a plate system including a plate with a locking element adapted to lock only a single bone screw (species (b)). Applicant submits that the Restriction Requirement mailed by

Application No. 10/802,906
Amendment dated August 7, 2006
Reply to Office Action of March 20, 2006

the Office during the prosecution of the '721 patent shows that the subject matter of the present application is patentably distinct from the subject matter of the '776 patent and the '586 patent.

Moreover, for the subject matter of the '776 patent in particular, Applicant submits that the claims of the '776 patent are patentably distinct from the claims of the present application because the claims of both the present application and the '776 patent meet the combination/subcombination test for distinctness. According to the MPEP:

"[t]he inventions are distinct if it can be shown that a combination as claimed:

(A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), and

(B) the subcombination can be shown to have utility either by itself or in other and different relations."

(MPEP § 806.05(c) (August 2001)).

The present application includes a claim to the combination having an implant including a locking element for locking at least two bone screws. Independent claim 1 of the '776 patent is directed to a locking element having "a first dimension and a second dimension" where "said second dimension" is "greater than said first dimension." Independent claim 56 of the '776 patent is directed to a locking element having "at least one flexible portion formed by at least one slot passing through at least a portion of said thickness of said locking element." Independent claim 111 of the '776 patent is directed to a locking element having a lower facing surface "being at least in part ramped and adapted to slide over at least a portion of a bone screw inserted into one of the bone screw receiving holes." Independent claim 166 of the '776 patent is directed to a locking element having a lower facing surface "being at least in part cammed and adapted to slide over at least a portion of a bone screw inserted into one of the bone screw receiving holes."

None of the features of independent claims 1, 56, 111, and 166 of the '776 patent are required for patentability of independent claim 7 of the present application. Accordingly, the part A of the test set forth above is satisfied. Moreover, Applicant

Application No. 10/802,906
Amendment dated August 7, 2006
Reply to Office Action of March 20, 2006

submits that the locking element claimed in the '776 patent has utility by itself. For example, the locking element claimed in the '776 patent can be part of an anterior cervical plate. Thus, part B of the test set forth above is satisfied. Accordingly, Applicant submits that both parts of the test for distinctness are satisfied and that the subject matter of the claims of the present application are patently distinct from the claims of the '776 patent.

Applicant submits that independent claim 7 is patentable and that dependent claims 8-41 dependent from independent claim 7, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: August 7, 2006

By: 

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Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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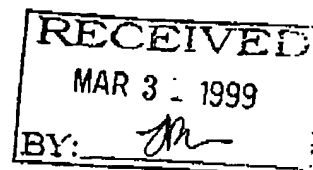
EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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EXHIBIT A

DOCKETED BY

2 - Mail Copy

Office Action SummaryApplication No.
09/022,293

Applicant(s)

Michelson

Examiner

Guy V. Tucker

Group Art Unit

3731

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 0 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-537 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-537 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Serial No. 09/022,293

-2-

Art Unit 3731

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-434, drawn to a bone plate, classified in class 606, subclass 70.
 - II. Claims 435-451, drawn to a method of treating a spine, classified in class 606, subclass 61.
 - III. Claims 453-459, drawn to a spinal ompressor, classified in class 606, subclass 61.
 - IV. Claims 460-470, drawn to a pilot hole former, classified in class 606, subclass 86.
 - V. Claims 471-490, drawn to a bone screw, classified in class 606, subclass 73.
 - VI. Claims 491-537, drawn to a locking element, classified in class 606, subclass 60.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions s II and (I,III,IV,V,VI) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as repairing fractured long bones.
3. Inventions I, III, IV, V and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention all the subcombinations have separate utility such as being used separately. See MPEP § 806.05(d).
4. Because these inventions are distinct for the reasons given above and have acquired a

EXHIBIT A

-3-

Serial No. 09/022,293

Art Unit 3731

separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. The embodiment of figures 1-30
- b. The embodiment of figures 47-59
- c. The embodiment of figures 71-79
- d. The embodiment of figure 83.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

EXHIBIT A

Serial No. 09/022,293

-4-

Art Unit 3731

of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Lewis Anten on 3-21-99 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Guy Tucker at telephone number (703) 308-3271. Examiner Tucker can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, examiner Tucker's supervisor, Michael Buiz, can be reached at (703) 308-0871. The fax number for Group 3730 is (703) 305-3590 or 3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 3730 receptionist at (703) 308-0858.

GVT
March 22, 1999

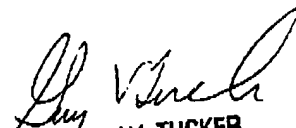

GUY V. TUCKER
PRIMARY EXAMINER
GROUP 3300

EXHIBIT A